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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,550	03/29/2004	Nobuko Yamamoto	00862.023526	1679

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

* MAIL DATE	DELIVERY MODE
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01/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,550	Applicant(s) YAMAMOTO ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0404;0405a;0405b;1006;0107</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, and of SEQ ID NO: 1, in the reply filed on November 2, 2007 is acknowledged. The examiner agrees with applicant's identification of claims 4-6 as being drawn to the elected invention (see the Response of November 2, 2007). Accordingly, claims 4-6 (to the extent that they are drawn to SEQ ID NO: 1) are under consideration.
2. Claims 1-3 and 7-49, as well as sequences other than elected SEQ ID NO: 1, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 2, 2007.

Claim Objections

3. Claims 4-6 are objected to because the claims encompass non-elected subject matter, specifically, SEQ ID NOs other than elected SEQ ID NO: 1. The claims should be amended such that they are drawn only to the elected invention.
4. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is drawn to a carrier "on which an infection detection probe included in the probe set of claim 5 is chemically immobilized." Thus, the claim does not actually further limit the probe set claimed in claim 5; rather, it embraces a carrier on which is immobilized, for example,

an individual probe selected from the probe set of claim 5. Thus, claim 6 does not require every limitation of claim 5, and is not a proper dependent claim.

5. Claim 4 is objected to because of the following informalities: the claim recites "gene originated in" rather than, e.g., "gene originating in", and recites "includes oligonucleotide..." rather than "includes an oligonucleotide...". Appropriate correction is required.

6. Claims 5-6 are objected to because of the following informalities: claim 5 recites "gene originated in" rather than, e.g., "gene originating in", and recites "includes at least one of infection detection probes each comprising oligonucleotide..." rather than, e.g., "includes at least one infection detection probe comprising an oligonucleotide...". Appropriate correction is required.

Information Disclosure Statement

7. The information disclosure statement filed April 12, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Accordingly, references DE 19915141 and DE 19941359 could not be considered. Additionally, the following references were not considered because copies of the references were not provided: WO 97/31114; EMBL Accession Nos AY126146 and AAL44979. It is noted that the examiner also has lined through duplicate citations of some documents.

Specification

8. The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a) and (a)(2). However, the specification fails to comply with one or more of the requirements of 37 CFR 1.821 through 1.825 because the specification recites sequences that lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR 1.821(d). See, for example, pages 32-37, 40-45, and 49-53. Appropriate corrections for compliance are required.

Claim Rejections - 35 USC § 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it is not clear whether the recitation "which includes oligonucleotide having one of the base sequences of SEQ ID Nos. 1 to 14 and complementary sequences thereof" is further limiting of the previously recited "infection detection probe" or of the previously recited "gene originating in" *S. aureus*. This rejection could be overcome by amending the claim to recite (in lieu of "aureus, which includes....") e.g., "aureus, wherein said probe includes..."

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US 5,474,796 A [12 December 1995]).

Claim 4 is drawn to a probe that includes an "oligonucleotide having one of the base sequences of SEQ ID Nos. 1 to 14 and complementary sequences thereof," such that the claim encompasses any probe including any "base sequence of" SEQ ID NO: 1 (i.e., SEQ ID NO: 1 or any subsequence thereof), and well as any sequence complementary thereto, wherein the probe "can detect a gene originated in *Staphylococcus aureus*." Claims 5 is drawn to a probe set including a probe having the structural characteristics noted above with regard to claim 4, which probe set "can detect a gene originating in *Staphylococcus aureus*." Claim 6 is drawn to a carrier on which a probe "included in the probe set of claim 5" is immobilized.

Brennan discloses a microarray comprising a complete set of all possible 10-mers (see entire reference, particularly Example 4, col 9, lines 48-60). As the set of 10-mers taught by Brennan includes all possible 10mers, Brennan's microarray inherently includes probes and probe sets meeting the structural requirements of the instant claims (i.e., including both a "base sequence of" SEQ ID NO: 1 and sequences complementary thereto). Further, the probes and probe set of Brennan could be used to "detect a gene originating in" *S. aureus* by methods known in the art, such as the sequencing by hybridization described by Brennan (see Example 5, col 9, line 14-col 10, line 5). It is noted that the claims are not drawn to, e.g., methods in which probes/probe sets are actually employed in a particular way, but rather merely require probes/probe sets that are able to "detect a gene originating in" *S. aureus* in some manner. Thus, Brennan anticipates the claimed invention.

13. Claims 4-6 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Hsu et al (US 2004/0010129 A1 [15 January 2004; filed 28 October 2002]).

As the Hsu et al reference qualifies as prior art under both 35 USC 102(a) and 35 USC 102(e), this rejection applies to the claims under both statutes.

Regarding claims 4-6, Hsu et al disclose a set of probes "for diagnosing *Staphylococcus aureus*," which probe set includes a probe comprising instant SEQ ID NO: 1 (see entire reference, particularly, page 2 paragraphs 13 and 15 [noting the sequence identified as "1-2", as well as claim 2). With further regard to claim 6, Hsu et al disclose biochips comprising their probe sets; see, e.g., paragraphs 18-19 and 52, and claims 23-25 and 28). Therefore, Hsu et al describe a probe, a probe set and a

carrier meeting both the structural and functional requirements of claims 4-6, and anticipate those claims.

14. With regard to the above rejection under 35 USC 102(a), it is noted that Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

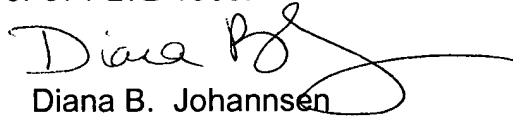
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Diana B. Johannsen
Primary Examiner
Art Unit 1634